



# ***Anthrax Vaccine Immunization Program***

**Individual's  
Briefing**



**Protecting  
the Individual**

SEP 10 2002

# Threat

- **Anthrax: the most likely biological warfare agent:**
  - Relatively easy and cheap to produce
  - Can be stored for a long time
  - Can be dispersed in a variety of ways
  - Odorless, colorless, tasteless, difficult to detect
- **Anthrax can cause widespread illness and death among unvaccinated, untreated and unprotected people.**
- **Vaccination is critical for your protection.**
- **This vaccination program is required, except for legitimate medical exemptions.**



SEPT 02

# Anthrax: Three Disease Types

## Cutaneous Anthrax

- Most common form; spores enter breaks in skin
- Responds well to antibiotics
- 5% to 20% of infected people die without treatment

## Gastrointestinal Anthrax

- Ingestion (e.g., eating undercooked, infected meat)
- Severe gastrointestinal symptoms
- 50% of infected people die even with treatment

## Inhalational Anthrax

- “Flu-like symptoms” early, rapid deterioration, then death
- After symptoms occur, almost 100% of unvaccinated, unprotected, and untreated people die
- About 50% die even with intensive care

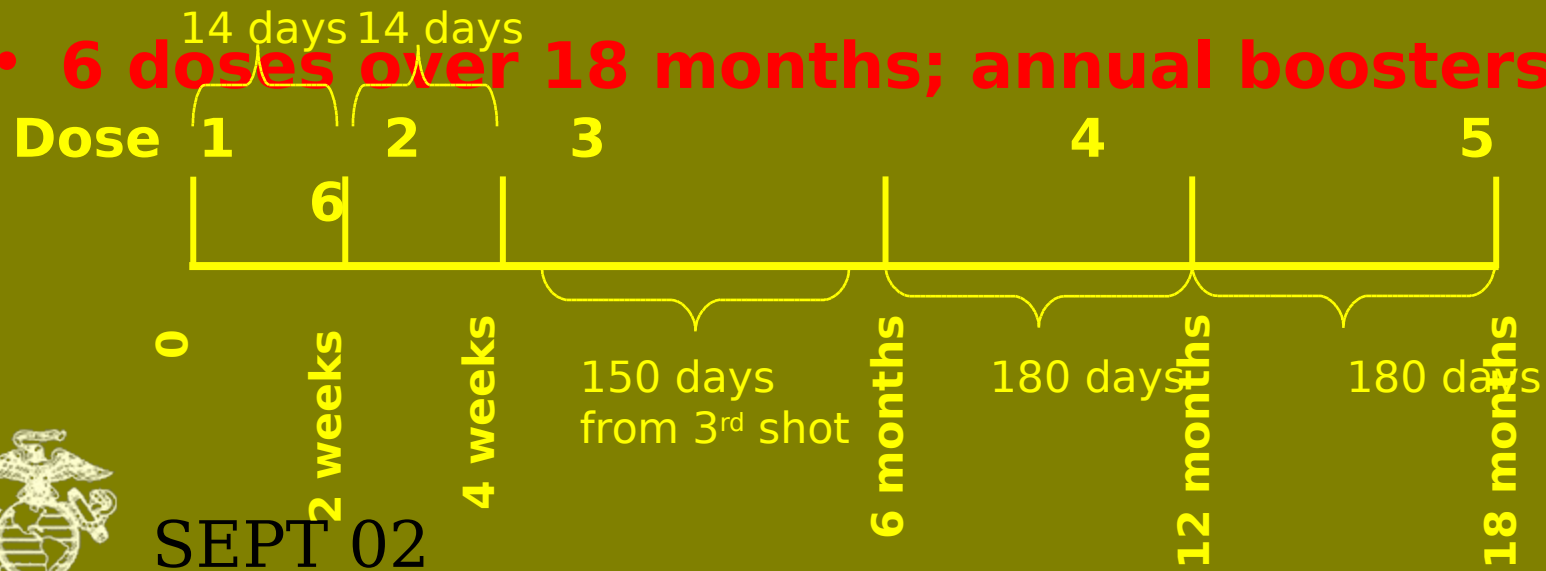


SEPT 02

# Anthrax Vaccine Facts

- **Manufactured by BioPort Corp., Lansing, Michigan**
- **FDA-licensed product since 1970; NOT an investigational new drug (IND); each lot FDA approved**
- **Inactivated, cell-free, made from anthrax strain that does not cause the disease**

• **6 doses over 18 months; annual boosters:**



SEPT 02

# Status of AVIP

- **Status:**
  - **FDA ruled anthrax vaccine is safe and effective regardless of route of anthrax exposure**
  - **Mar 98 to Jan 04: Over 3.7 million doses to over 1 million people**
  - **18 human safety studies**
  - **7 reviews by independent panels of civilian physicians, each affirming safety and effectiveness of the vaccine**
  - **Dec 03 injunction on AVIP has been lifted and vaccinations legally continue**

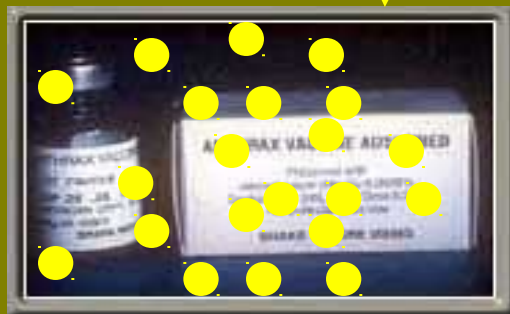


# How Anthrax Vaccine Prevents Disease

**Anthrax Bacteria**

**Protective Antigen (PA)**

**filtered**



**Vaccine contains PA, extracted from weakened nonlethal anthrax bacteria.**



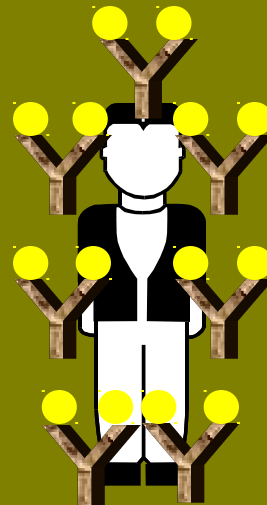
SEPT 02

**Disease**

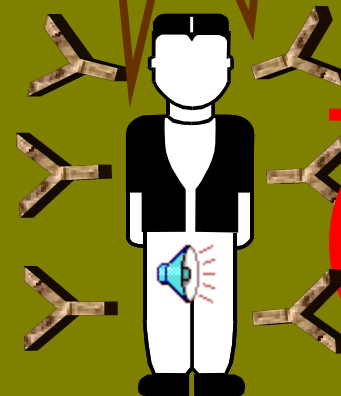
**Lethal Factor**

**Exposure to**

**Edema Factor**



**Immune system develops antibodies (Y) to PA, protection from disease.**



**Antibodies "neutralize" PA, common part of anthrax toxins.**

**Disease & Death**

# Anthrax Vaccine

## Effectiveness

- **Human clinical trials in the 1950's: 92.5% effective**
- **Multiple animal studies: 95% protective in Rhesus monkeys, and 97% in rabbits**
- **Protective antigen (PA) is the common disease-causing protein in all anthrax strains**
- **Blocking PA blocks the disease: all strains**
- **National Academy of Sciences: Anthrax vaccine is “an effective vaccine for the protection of humans against anthrax,**



SEPT 02

# Exemptions

**Some people should not get anthrax vaccine.**

**Temporary medical exemptions include:**

- Short term immunosuppressive therapy
- Serious acute diseases, injuries, surgery
- Pregnancy
- Medical evaluation or condition pending

**Permanent exemptions include:**

- Severe reaction after previous dose of anthrax vaccine
- HIV or other chronic immune deficiencies
- Immunity based on previous anthrax infection





# Anthrax Vaccine Safety

- **More than 1 million people have received anthrax vaccine**
- **Injection-site reactions common:**
  - 30% of men, 60% of women have injection-site reactions
  - Redness, itching, swelling, burning, soreness or pain
- **Systemic symptoms (away from injection site):**
  - 5% to 35% of both genders; more by women
  - Muscle/joint aches, chills, low-grade fever, headaches, nausea, rashes, fatigue, swelling may extend below elbow
- **Acute allergic reactions after any vaccine, 1 in 100,000 doses**
- **Deaths have been reported rarely after any vaccine**



SEP 1 02

# Adverse Event Reporting

- **Vaccine Adverse Event Reporting System (VAERS):**
  - FDA and CDC review 100% of adverse-event reports
  - Reviewed by independent panel of expert civilian physicians for 4 years
- **DoD requires a VAERS Form submission for:**
  - Loss of duty 24 hours or longer ( $\geq$  1 duty day)
  - Hospitalization
  - Suspected vaccine vial contamination
- **Other submissions are encouraged.**
- **Anyone can submit a VAERS Form!**
- **VAERS Forms may be obtained from:**
  - Your clinic, 1-800-822-7967, or [www.vaers.org](http://www.vaers.org)



# Reserve Component Adverse Events

- **Adverse events after DoD- or USCG-directed vaccinations are line-of-duty conditions**
- **Someone with an adverse event in a non-duty status possibly associated to any vaccination:**
  - Seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
  - Must report the event to your unit commander or designated representative as soon as possible
  - Consider VAERS submission
- **Commander will determine Line of Duty and/or Notice of Eligibility status, if required**



# Key Messages

- Your health & safety are our #1 concerns
- Anthrax vaccine is safe and effective
- The threat of anthrax is deadly and real
- Vaccination offers a layer of protection, in addition to antibiotics and other measures, needed for certain members of the Armed Forces



# More Information

- **Chain of Command / Supervisors**
- **Military Vaccine (MILVAX) Agency**
  - Website: **[www.anthrax.mil](http://www.anthrax.mil)**
  - Toll-Free: **877.GET VACC**
- **Centers for Disease Control and Prevention (CDC):**
  - Website: **[www.bt.cdc.gov](http://www.bt.cdc.gov)**
  - CDC National Immunization Hotline:  
**800.232.2522**
- **Walter Reed Vaccine Healthcare Center:**  
**202.782.0411 ([www.vhcinfo.org](http://www.vhcinfo.org))**
- **Call your local Military Medical Treatment Facility (MTF) -OR- if Reserve Component seeking care at a civilian facility, contact the Military Medical Support Office (MMSO):** **888**



SEPT 02

13